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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,045	06/22/2005	Frans Eduard Janssens	JAB1733f	8682

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,045	JANSSENS ET AL.	
	Examiner	Art Unit	
	EMILY BERNHARDT	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-17* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of applicants' response filed on 4/2/08 the following applies.

Rejoinder of nonelected process claims 16 and 17 is premature as corresponding compound claims remain rejected for reasons set forth below. Should said claims be found allowable at a later date, note that claim 17 is an improper multiple dependent claim as it depends on different set(s) of claims to different features. See MPEP 608.01 (n). Also for claim 16 the period should appear **after** the reaction sequence.

Claims 11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 11 has been amended to recite "a method of treating " which is a statutory claim but is of indeterminate scope for the following reasons. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to NK antagonistic activity involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular compound is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether

applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

2. In amending claim 15 to an independent claim, many of the variables are not defined therein. See variables appearing on the last 4 lines.

The objection to the specification has been obviated by applicants' amendments incorporating text which was previously only referred to by way of citing a WO publication. It is noted that US'743 newly added is part of the same patent family as EP'456.

Claims 1, 3-8 and 11-15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for scope in claims 2 and 9, does not reasonably provide enablement for remaining scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. While applicants have amended the claims at R^2, the scope at Het^2 is also huge compared to what has been made and tested. It is further exacerbated by the varying ring sizes of both azine rings as emphasized previously.Note in claim 1 the size of the central rings can be 5-7 membered whereas only the azine rings have been made and tested.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for uses embraced in claim 12, does not reasonably provide enablement for scope covered in the generic claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claim

amended to treatment of tachykinin-mediated conditions from a reading of the specification (see pp.18-22), includes (but is not limited to) whole classes of disorders such as cognitive, eating, neurodegenerative, gastrointestinal, all skin disorders, all types of vasospastic diseases as well as collagen diseases, all forms of sexual dysfunction. The notion that NK-1 or NK-2 or NK-3 antagonists have such a range of uses is not remotely warranted given the current state of the art such as Sanger or Ohnmacht, provided with this action which show limited applications for treating uses in claim 12 . Note Hoffman V. Klaus 9 USPQ2d 1657 regarding the standard of testing that is necessary to establish the likelihood of *in vivo* use. Also see Ex parte Powers 220 USPQ 925. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of ***in vivo*** efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907.

Note also the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition which considers factors such as:

1) Breadth of the claims- The claims cover (but are not limited to) to a huge variety of unrelated disorders ;

2) Level of skill in this art- there are no drugs that are either NK-1, NK-2, NK-3 antagonists or a mixed profile of all 3 which have such a spectrum of clinical applications and thus the level of skill is low ;

3) State of the prior art- as far as the examiner is aware there are no compounds similar in structure which have been reported to be preclinically much less clinically

active for such a range of uses;

4) Working examples- There are no test(s) directed to the many uses pointed out above which are art-recognized for predicting *in vivo* efficacy .

Thus in view of the above the rejection is being applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 and 11-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO'428 and WO'772 for reasons of record. A certified copy of applicants' foreign priority paper has been obtained. A review of the document vs what is being claimed herein shows that entire claimed subject matter is not adequately described in said priority papers. The instant scope at Y,L and scope of substituents permitted in Het^2 is broader than that described in priority papers. For the species in claim 9 only 1^{st}, 2^{nd}, 4^{th} and last 3 are seen in the priority document. As discussed in the previous action compliance with 35 USC 112, par.one must be demonstrated for 119 priority . Thus for the lack of sufficient description as well as enablement as discussed in the above 112 rejection, the WO publications remain competent references.

Claims 1-9 and 11-14 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/527821 (recently allowed) for reasons of record. Applicants do not traverse this rejection but state their possible intent to file a terminal disclaimer should claims be otherwise in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/

Primary Examiner, Art Unit 1624

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